

# **Exhibit A**



**G2 EXPRESS™ Filter System –  
Femoral and Jugular/Subclavian Delivery Kits**

**Special 510(k) Submission**

**March 7, 2008**

**CONFIDENTIALITY STATEMENT**

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Special 510(k)

G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits

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## Indications for Use

510(k) Number (if known):

Device Name: G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits

### Indications for Use:

The G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- G2 EXPRESS™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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